

REMARKS

The Office Action of February 10, 2009 has been carefully considered.

Claims 16-30 stand rejected under 35 USC 103(a) over Cooper et al in view of Chantler et al.

The claims have now been amended to change "spermicidal antiseptic" and "antiseptic" to "spermicide," as a more accurate recitation of the invention.

Claim 16 has also been amended to recite that the lubricant composition "consists essentially of" the recited components, to which water, alcohol and flavors have been added as optional components. Water is present in every example, the exemplified lubricants being water-based, alcohols are disclosed at page 8, lines 9-10 of the specification, and flavors are mentioned in the parent application 07/978,671, incorporated by reference.

The Office Action takes the position that Cooper et al teaches each and every element of the invention, and the Applicant is claiming a new use for an old compound.

While the present application is in essence directed to a new use for old compounds, the claims are new and novel as the claims are method claims, and the claimed method is not suggested by the cited references. Moreover, Cooper et al does not teach each and every element of the claimed invention, as alleged in the Office Action.

Cooper et al was first filed in 1977-1978, and Chantler et al was filed in Great Britain in 1983. At that time, the problem which the present invention is designed to overcome was not yet known. Therefore, neither Cooper et al, nor the combination of Cooper et al and Chantler et al could have suggested the solution claimed in the present invention. These patents must be taken in the context of the art at the time.

The inventor of the present application was the first to

disclose that the HIV virus will penetrate the vaginal wall through ulcerations caused by fungal infections which result from the absence of natural flora in the vagina, destroyed by the spermicide; this flora would naturally control any fungus in the vagina. The fungicide, therefore, acts *in vivo* to destroy the fungus.

Cooper et al discloses that amphipatic amines act as spermicidal agents, and teaches that these agents may be used in compositions that contain "supplementary topical antiseptic and germicidal agents which are conventionally used in topical contraceptive compositions in addition to the amphipathic amine" (col 8, line 67- col. 9, line 1). Among the agents mentioned is nonoxynol-9. Chantler et al was cited to show that chlorhexidine was also known for this purpose.

The composition may also contain lubricants and additional adjuvants, including methylparaben and propylparaben.

The rejection is therefore based on the allegation that Cooper et al teaches a spermicidal lubricant composition which contains an amphipathic amine, and which can also contain an additional spermicide according to the invention, and a fungicide.

It is important to note initially that amphipathic amines are not thought to be spermicides according to the invention. The invention requires that the claimed spermicides destroy natural flora in the vagina and permit thereby growth of fungi causing ulceration of the vagina.

There is no evidence that this effect occurs with the amphipathic amines claimed by Cooper et al. In the testing on rabbits, Cooper et al states at col. 8, lines 6-11:

The vagina of all females tested are examined visually at autopsy and the contents of the posterior and anterior portions of the vagina are examined microscopically for any signs of bleeding,

surface hemorrhage or of excessive sloughing or desquamation of the epithelium of the vagina. None of the females examined, controls or amine instilled females, show any sign of bleeding or surface hemorrhage.

Moreover, it is stated at col. 8, lines 31-36:

No irritating effect of the tested amines on the vagina is observed in the in vivo test. It is evident from these test results that the skin-irritating properties, which the free amines are known to possess, are eliminated if these amines are contained in a composition which exhibits a pH-value which is in the range of the vaginal pH.

Since the spermicidal agents of Cooper et al are non-irritating, Applicant submits that they do not fall within the definition of the invention, and Cooper et al can only suggest the invention, if at all, when the spermicidal agent is combined with other agents which are irritating, and which would require a fungicide to kill fungi which proliferates in the vagina in the absence of natural flora.

Claim 1, however, has now been amended to recite that the lubricant composition *consists essentially of* the lubricant, spermicide and fungicide (and optionally water, alcohol and flavor). The amphipathic amines of Cooper et al are believed to be excluded by this language, since amphipathic amines are disclosed by Cooper et al to be non-irritating.

Cooper et al, even in combination with Chantler et al, discloses no compositions which contain only an irritating spermicide, in combination with a lubricant and a fungicide. Moreover, there is no suggestion of using such a composition to reduce the likelihood of a fungal infection caused by the spermicide killing the natural flora of the vagina.

Methyparaben and propylparaben are no more that optional

adjuvants taken from a long list of optional adjuvants disclosed by Cooper et al. It is not even clear why they would be necessary, since the compositions of Cooper et al already contain antiseptic agents.

It is important to remember that Cooper et al was filed as an application for the first time in 1977-1978, well prior to the recognition of AIDS. Nothing in the cited art suggests that at that time, there was any knowledge that spermicidal compositions caused fungal infections, and that such fungal infections could lead to more serious infections.

It is further pointed out that while Cooper et al discloses the presence of methylparaben in the compositions of Example 2, no fungicide is present in Example 3 or Example 4, indicating that this is not an essential ingredient in a spermicidal composition for application to the vagina. To the contrary, according to the invention, the fungicide does not act as a preservative which may or may not be necessary, but is a critically important part of the composition based upon its *in vivo* action which is not disclosed or suggested by the cited references.

Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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